REMARKS

This document is submitted in response to the Final Office Action dated July 6, 2010 ("Final Office Action"). Claims 1, 3-10, 12, and 14-21 will be pending and under examination. Applicants respectfully request that the Examiner reconsider this application in view of the following remarks.

The Examiner maintains the rejection against claims 1, 3-10, 12, and 14-21 for obviousness on a number of grounds. Applicants will address each of them below.

I

The Examiner rejects claims 1, 3, 7-10, 12, 16-18, and 20-21 for obviousness over US 6945411 to Bormann *et al.* ("Bormann") in view of EP 0542655 by Majurel ("Majurel"). See the Office Action, page 2, item 2. Applicants respectfully traverse and will discuss independent claim 1 first.

Claim 1 is drawn to a filter device for the depletion of the leukocyte content from a blood product. The filter includes a housing having an inlet and an outlet. Within the housing, more than two porous elements are configured to remove leukocytes. Each of the porous elements includes one or more layers of a filtering material and each of the porous elements has a different hydrophilicity. The more than two elements are arranged in the filter device such that any of the porous elements has a higher hydrophilicity than a successive porous element in a direction of flow, from the inlet to the outlet, of the blood product through the filter device. In other words, a negative hydrophilicity gradient exists between the two porous elements and along the direction of the flow.

In their last response filed on April 9, 2010, Applicants pointed out that Bormann does not teach or suggest a negative hydrophilicity gradient between the two porous elements as required in claim 1 and that, to the contrary, it teaches a device has no hydrophilicity direction or a hydrophilicity direction opposite to that required in claim 1. Therefore, Bormann teaches one skilled in the art away from the filter device of claim 1. Majurel, the secondary reference, does not rectify these defects of Bormann, as it does not state that hydrophobicity is increased between two porous elements. Thus, the two references, alone or in combination, do not render claim 1 obvious.

The Final Office Action agrees with Applicants arguments regarding Bormann, but counters that Majurel would rectify the defects of Bormann. As such, the Examiner concludes that one of ordinary skill in the art would combine Bormann and Majurel so as to arrive at the filter device of claim 1. See the Office Action, page 3, lines 3-4. Applicants respectfully traverse.

I-A

To support her conclusion, the Examiner states that "Majurel discloses a filtration device [that has a filter, which includes three] different layers having increasing hydrophobicity from inlet to outlet." See the Final Office Action, page 2, lines 26-27.

Applicants would like to point out that the Majurel device has one, single filter "consisting of a composite membrane" with three layers having increasing hydrophobicity. See the Abstract. That is, Majurel teaches a device having one element. In contrast, claim 1 requires at least two porous elements between which a negative hydrophilicity gradient exists along the direction of the flow. Majurel dose not teach such more than two porous elements, much less a negative hydrophilicity gradient between the two elements as required in claim 1. As mentioned above, Bormann does not teach or suggest this negative hydrophilicity gradient between the two porous elements. Thus, contrary to the Examiner's position, Bormann and Majurel, alone or combined, would not allow one of ordinary skill to arrive at the filter device of claim 1

Even if one of ordinary skill would combine Bormann and Majurel by using a plurality of the Majurel filter element in the Bormann device, the resultant filter would be like the filter shown in Figure 3 of Bormann. As discussed in Applicants' last response, the filter shown in Figure 3 of Bormann has an alternating arrangement and, as result, no overall negative hydrophilicity gradient is achieved. Again, it follows that the alleged combination of Bormann and Majurel would not arrive at the filter device of claim 1.

I-B

To support her conclusion, the Examiner asserts that "to shift location of parts [from Majurel] when the operation of the device is not otherwise changed is within the level of ordinary skill in the art." See page 2, last line to page 3, first line. It appears to

be the Examiner's belief, when one "shift[s]" and uses the Majurel filtration device/element in the Bormann device to arrive at the filter device of claim 1, the operation of the claimed device "is not otherwise changed."

Applicants disagree. Contrary to her belief, the hypothetical shifting would change the operation of the claimed device. More specifically, Majurel does not use its filter, which has three layers, in isolation within the Majurel device; the filter is stated to **require** a further "***essential***" element in combination with the layers, namely the "filter consist[s] of a composite membrane" which is **coated with glass microbeads having 2 to 3 mm in thickness**. See the Abstract and column 2, lines 14-21.

In view of this teaching, one skilled person would clearly recognize that the required addition of glass beads to a filter membrane would undoubtedly hinder at least the core inventive technical features of the filter device of claim 1. For example, the gradient in claim 1 is so established that "liquid pressure is distributed evenly on the following more hydrophobic layers" and the "described arrangement improves the air elimination from the filter material, avoiding blood flow channeling, **leading to a better leukocyte removal efficiency.**" See page 8, last paragraph to page 9, first full paragraph of the Specification. Both of these desired features, which exist as a consequence of the negative hydrophilicity gradient, would be compromised, if not completely eliminated, with the introduction of glass beads. In other words, the operation of the claimed device would be "otherwise changed." Accordingly, one skilled in the art would not combine Bormann and Majurel in the manner believed by the Examiner.

I-C

Finally, to support her conclusion, the Examiner further asserts that "it would be obvious to one of ordinary skill in the art to use the teachings of these [Bormann and Majurel] references to arrive at applicant's invention because it produces no more than predicable result." See the Office Action, page 3, lines 3-15.

Applicants disagree. The Bormann device is used for the depletion of the leukocyte and platelet content from blood products. See column 1, lines 11-12. In contrast, the Majurel device is used for separation and determination of agglutinated

erythrocytes. See the Abstract.[1] It follows that the elements in both devices are selected accordingly and assembled specifically so as to achieve the different stated uses, respectively.

In view of the different structures and resultant different uses of the Bormann device and the Majurel device, one skill in the art would NOT be able to readily predict the use of a HYBRID device having different components from both the Bormann device and the Majurel device. In other words, contrary to the Examiner's assertion, combining Bormann and Majurel in the manner suggested by the Examiner would not produce a result that is readily predictable.

For the reasons and facts set forth above, Applicants submit that claim 1 is non-obvious over Bormann in view of Majurel. Claims 3, 7-10, 12, 16-18, and 20-21 12 ard 20-21 also require the above-discussed negative hydrophilicity gradient between two porous elements. For at least the same reasons, these claims are also not obvious over the two references.

II

The Examiner rejects claims 4-6, 14, 15, and 19 for obviousness over Bormann in view of Majurel and further in view of US Patent No. 4925572 to Pall ("Pall"), US Patent No. 5298165 to Oka *et al.* ("Oka"), or US Patent No. 5190657 to Heagle *et al.* ("Heagle"). See the Final Office Action, pages 4-5, items 14, 17, and 20.

All of the rejected claims depend from claim 1. As discussed above, Bormann and Majurel do not render claim 1 obvious. Neither of Pall, Oka, and Heagle rectifies the defects of Bormann and Majurel. Thus, all of the cited references, alone or in combination, do not render claim 6, 14, 15, or 19 obvious.

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[1] As pointed out in Applicant's last response, Majurel does not teach a *leukocyte* depletion filter; the disclosed filter does not even appear to be suitable for filtering/removing leukocytes from a blood sample, because, according to Majurel, only agglutinated erythrocytes are retained, while the rest of the sample applied to the device (the mobile phase or "la phase mobile") is removed (*see* page 2, col. 2, lines 40-42 and page 3, col. 1, lines 22-29). Since Majurel is restricted to the separation of agglutinated erythrocytes from the mobile phase, and since leukocytes are not even addressed, one skilled in the art would conclude that the Majurel device is not suited for the removal of leukocytes.

CONCLUSION

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

Please apply any other charges to Deposit Account No. 50-4189, referencing Attorney Docket No. 7B901-002US1.

Respectfully submitted,

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